

REMARKS

I. Status

Claims 1-15 are pending in the application. Claims 1 and 13-15 are currently amended to correct certain typographical errors and for greater clarification. New claims 16-18 are being presented, which further define the methods and pharmaceutical compositions from which they depend. New claims 19-22 further define the methods from which they depend to be administered in combination with one or more additional agents which modulate a mammalian immune system or with antiinflammatory agents. Support for the amendments and new claims can be found throughout the specification, e.g., at the claims as originally filed and at page 6, lines 13-23 of the specification. No new matter is being added.

Claims 1-15 stand rejected under 35 U.S.C. § 112, ¶2. Claims 1-15 stand rejected under 35 U.S.C. § 112, ¶1 with regard to enablement. Claim 15 stands rejected under the obviousness-type double patenting doctrine separately over claims 1-4 of U.S. Patent No. 6,627,754 and claims 1-4 of U.S. Patent No. 6,890,929. Claims 1-15 stand rejected under the obviousness-type double patenting doctrine over claims 4 and 5 of U.S. Patent No. 6,956,041. Claims 1-15 provisionally stand rejected under the obviousness-type double patenting doctrine separately over claims 27-48 of U.S. Serial No. 11/211,217 and claims 7, 8, 10, 12-16, and 19 of U.S. Serial No. 11/064,873. Claim 14 is objected to as being a substantial duplicate of claim 1. Applicant traverses the rejections.

II. Claims 1 and 14 Are Not Substantial Duplicates

The Examiner objects to claim 14 as being a substantial duplicate of claim 1. Applicant traverses this objection because claim 14 is patentably distinct from claim 1. Notably, claim 1 defines *inter alia* a method of treating *chronic* organ transplant rejection, whereas claim 14 defines

inter alia a method of treating *acute* organ transplant rejection. Applicant respectfully reminds the Examiner that the doctrine of claim differentiation creates a presumption that each claim in a patent has a different scope. *Comark Communications v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998). Absent the Examiner effectively rebutting this presumption, Applicant deems claims 1 and 14 as being sufficiently differentiated.

III. Claims 1-15 Are Definite

Claims 1-15 stand rejected under § 112, ¶2 because the Examiner asserts the term “including” as used in claims 1, 14, and 15 is open and implies more than what is being positively recited therein. Applicant respectfully traverses the rejection because those of skill in the art given the benefit of the present disclosure would readily realize the metes and bounds of the term “including a human” as recited in each of the cited claims. The Examiner is respectfully reminded that claims which define patentable subject matter with a reasonable degree of particularity and distinctness should be allowed. M.P.E.P. § 2173.02 (8th Ed., Rev. 3) (emphasis in original). Here, each of the cited claims defines “a mammal, including a human”. Certainly, those of skill in the art given the benefit of the present disclosure would understand the meaning and scope of the term “mammals” and would appreciate that humans are a type of mammal. As such, the scope of the cited claims is clear, and the cited claims do not reasonably imply more than what the plain meaning of the term at issue defines. Claims 2-13 are definite at least by virtue of each claim being directly dependent from definite claim 1. Thus, removal of the present rejection is respectfully requested at this time.

IV. Claims 1-15 Are Enabled

Claims 1-15 stand rejected under 35 U.S.C. § 112, ¶1 with regard to enablement. In particular, the Examiner asserts at page 3 of the Office Action that the specification does not reasonably provide enablement for the prevention of acute organ transplant rejection even though the Examiner admits that the specification is enabling for the treatment of acute organ transplant rejection. Applicant respectfully traverses the rejection at least because those of skill in the art given the benefit of the present disclosure would know how to make and use the inventions defined by the cited claims without undue experimentation. Nevertheless, solely to advance the prosecution of the present application, independent claims 1, 14, and 15 currently are amended to delete the term “or preventing” without prejudice. In view of the Examiner’s comments at page 3 of the Office Action, the current rejection is deemed overcome.

V. Double Patenting

The Examiner raises numerous obviousness-type double patenting rejections, which are discussed in turn.

Claim 15 stands rejected under the obviousness-type double patenting doctrine over claims 1-4 of U.S. Patent No. 6,627,754. Applicant traverses this rejection. Nevertheless, solely to advance the prosecution of the present application, Applicant is filing herewith a terminal disclaimer, which the Examiner states at page 7 of the Office Action can be used to overcome the present rejection. Thus, removal of this aspect of the rejection is appropriate.

Claim 15 also stands rejected under the obviousness-type double patenting doctrine over claims 1-4 of U.S. Patent No. 6,890,929 (“the ‘929 patent”). Applicant traverses this rejection at

least because the Examiner has not satisfied the burden of establishing that claims 1-4 of the '929 patent teach or suggest each and every element of claim 15. Instead, the Examiner merely states in a conclusory manner at pages 7-8 of the Office Action, "Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical composition embraced in the instant claim would be obvious over the compound claims 1-4 of US 6,890,929." The Examiner is respectfully reminded that the Examiner initially bears the burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not support a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. M.P.E.P. § 2142 (8th Ed., Rev. 3). In view of the Examiner's apparent lack of factually supporting the *prima facie* conclusion of obviousness, the rejection is deemed overcome.

Claims 1-15 stand rejected under the obviousness-type double patenting doctrine over claims 4 and 5 of U.S. Patent No. 6,956,041. Applicant traverses this rejection. Nevertheless, solely to advance the prosecution of the present application, Applicant is filing herewith a terminal disclaimer, which the Examiner states at page 7 of the Office Action can be used to overcome the present rejection. Thus, removal of this aspect of the rejection is appropriate.

Claims 1-15 provisionally stand rejected under the obviousness-type double patenting doctrine over claims 27-48 of U.S. Serial No. 11/211,217. In view of the issuance of U.S. Serial No. 11/211,217 on August 15, 2006 as U.S. Patent No. 7,091,208, Applicant is treating this rejection as an actual rejection rather than a provisional rejection. Applicant traverses this rejection. Nevertheless, solely to advance the prosecution of the present application, Applicant is filing herewith a terminal disclaimer, which the Examiner states at page 7 of the Office Action can be used to overcome the present rejection. Thus, removal of this aspect of the rejection is appropriate.

Claims 1-15 provisionally stand rejected under the obviousness-type double patenting doctrine over claims 7, 8, 10, 12-16, and 19 of U.S. Serial No. 11/064,873. In view of the early stage of prosecution of the cited application and the outstanding rejections in the present application, Applicant respectfully requests that this aspect of the double patenting rejection be held in abeyance until at least the present application is otherwise in condition for allowance. Should the Examiner deem that this double patenting rejection continue to be relevant when this application otherwise is in condition for allowance, the Examiner is requested to provide Applicant with an opportunity to substantively address such a rejection at that point in time.

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VI. Conclusion

Having addressed all outstanding issues, Applicant kindly requests removal of all rejections and allowance of all pending claims at this time. To the extent the Examiner believes it would facilitate allowance of this case, the Examiner is urged to call the undersigned at the number below.

Applicant believes a fee is associated with the present filing, which is detailed in form PTO/SB/17 filed herewith. To the extent an additional fee is due, the Commissioner is hereby authorized by this paper to charge any required fees or credit any overpayment to Deposit Account 16-1445.

Respectfully submitted,



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